

Update Instructions

SP030/05/S

Error using the correct and rearrange function

Reason for update: **Safety**

Urgency for update: ☒ Immediate ☐ Within months

Intranet update available? ☐ Yes ☒ No

Remote update feasible? ☐ Yes without CSE (Category 2) ☐ Yes, with CSE (Category 1) ☒ No

Materials for logistic update required? ☐ Yes ☒ No

Materials free of charge? ☐ Yes ☒ No

Return of parts? ☐ Yes ☒ No

Estimated completion time: 0.5 hour(s) Number of CSE's: 1

Customer application training? ☐ Yes ☒ No

Systems/Products affected/System identifying IVK

Name	Material No.	Serial No.
ARCADIS Varic	8080017	see list on page 2
ARCADIS Orbic	8081080	see list on page 2

Remark:

Components affected/to be modified/IVK

Name	Material No.	Serial No.	Component status affected
n.a.	n.a.	n.a.	n.a.

Remark:

Chg. Ref. No.: 165391
Name: Arnold
Dept.: CS PS SP

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Document Revision Level

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Systems / products affected

Systems ARCADIS Varic 8080017, delivered to and installed in the USA.

Serial numbers:

10002, 10007, 10013, 10014, 10015, 10017, 10020, 10021, 10027, 10028, 10030, 10031, 10033, 10034, 10035, 10036, 10037, 10038, 10043, 10044, 10062, 10075, 10081, 10085, 10086, 10087, 10090, 10095, 10096, 10101, 10107, 10109, 10110, 10111, 10115, 10116, 10124, 10127, 10128, 10129, 10131, 10132, 10146, 10152, 10154, 10158, 10159, 10160, 10161, 10162, 10163, 10165, 10168, 10169, 10170, 10178, 10181, 10182, 10185, 10191, 10195, 10196, 10197, 10198, 10199, 10200, 10201, 10203, 10204, 10211, 10215, 10216, 10218, 10220, 10221, 10222, 10224, 10225, 10230, 10231, 10232, 10234, 10236, 10239, 10241, 10242, 10244, 10245, 10246, 10247, 10249, 10257, 10258, 10259, 10260, 10261, 10263, 10264, 10265, 10266, 10267, 10268, 10271, 10273, 10274, 10276, 10278, 10279, 10280, 10281, 10283, 10284, 10287, 10289, 10290, 10291, 10293, 10300, 10327, 10328, 10336, 10337, 10353, 10364, 10381

Systems ARCADIS Orbic 8081080, delivered to and installed in the USA

Serial numbers:

20004, 20006, 20007, 20008, 20009, 20010, 20011, 20012, 20013, 20014, 20015, 20023, 20024, 20030, 20033, 20034, 20036, 20037, 20039, 20040, 20041, 20043, 20046, 20047, 20048, 20049, 20051, 20052, 20053, 20054, 20055, 20056, 20057, 20058, 20059, 20060, 20061, 20062, 20063, 20064, 20065, 20068, 20069, 20070, 20071, 20072, 20074, 20075, 20076, 20078, 20080, 20082, 20104, 20106, 20107, 20108, 20110, 20112, 20114, 20115, 20116, 20124, 20125, 20128, 20130

Reason for the Update

The image system allows the user to change patient information by using the correct and rearrange function. If the correct and rearrange function is used on a closed patient while an active patient is still open, an error could occur such that a study (scenes and/or images) from the active patient is stored under the name of the patient from the closed study.

If this error occurs, the images of the active patient can no longer be found. They will be located in a separate folder under the closed patient's name. However these images are still available.

To prevent this potential problem, the customer safety advisory letter informs the customer that the correct and rearrange function must not be used on closed patients while an active patient is still open.

Prerequisites

n.a.

Special Tools / Documents

n.a.

Ordering Information

n.a.

Contents of the Update Kit

n.a.

Return of Parts

n.a.

Distribution of the Customer safety advisory letter

- Duplicate the Customer safety advisory letter.
- Distribute the Customer safety advisory letter immediately by registered mail with confirmation of delivery.

Report

- The update is reported as follows:
 - The modification reply report has to be prepared by authorized personnel using an application on the Intranet.

Changes to Previous Version

n.a.

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CUSTOMER SAFETY ADVISORY

– Re: Error using the Correct and Rearrange function with the ARCADIS Orbic and Varic

Dear Radiology Director:

This letter is to inform you of a potential problem when saving patient studies on your ARCADIS Orbic or Varic X-Ray System.

What is the problem and when does it occur?

Your ARCADIS Orbic and Varic allows users to change patient information by using the Correct and Rearrange function. If the Correct and Rearrange function is used on a closed patient while an active patient is still open, an error could occur such that a study (scenes and / or images) from the active patient is stored under the name of the patient from the closed study.

What is the potential risk and what can the user do to minimize the risk?

If this error occurs, the images of the active patient will still be available but can no longer be found because they will now be located in a separate folder under the closed patient's name.

To prevent this potential problem, we urge you that the Correct and Rearrange function must not be used on closed patients while an active patient is still open.

How will this problem be resolved?

This problem will be resolved with a software update, scheduled for release in the Spring 2006.

We appreciate your understanding and cooperation with the safety advisory and ask that you instruct your personnel immediately. Please ensure that this safety advisory is inserted into your Operator's Manual where it should remain until the software update is performed.

Sincerely,
Siemens Medical Solutions



Holger Schmidt
President of Med SP



Karsten Belohlavek
Head of Product-Lifecycle-Management

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